United States Patent [19]

Hessel

[11] **4,375,813**

[45] **Mar. 8, 1983**

[54] **MEDICAL FLUID FLOW RATE CONTROLLING DEVICE**

[75] Inventor: **Stephen R. Hessel**, Monroe, Conn.

[73] Assignee: **Delmed, Inc.**, Canton, Mass.

[21] Appl. No.: **233,095**

[22] Filed: **Feb. 10, 1981**

[51] **Int. Cl.**[3] **A61M 5/14**

[52] **U.S. Cl.** ..... **128/214 C**; 128/227

[58] **Field of Search** ..... 128/214 R, 214 C, 214 G, 128/214.2, 227

[56] **References Cited**

U.S. PATENT DOCUMENTS

1,205,410	11/1916	Tenney .	
1,338,782	5/1920	Lindahl .	
1,427,455	8/1922	Gates .	
1,844,342	2/1932	Berman .	
2,090,273	8/1937	Wagner	137/68
2,254,833	9/1941	Ashkenaz	128/213
2,479,786	8/1949	Stevens	73/216
2,865,534	12/1958	Barnes	222/66
2,954,028	9/1960	Smith	128/214
2,971,366	2/1961	Tomkow	73/3
2,989,052	6/1961	Broman	128/214
3,001,397	9/1961	Leonard	73/194
3,017,885	1/1962	Robicsek	128/214
3,034,504	5/1962	Winsor et al.	128/214
3,037,384	6/1962	Good	73/211
3,049,918	8/1962	Sparkuhl	73/209
3,101,710	8/1963	Koehn	128/214
3,157,481	11/1964	Bujan	55/417
3,166,107	1/1965	Swenson et al.	141/145
3,198,009	8/1965	Fishman et al.	73/211
3,207,372	9/1965	Evans	222/67
3,216,418	11/1965	Scislowicz	128/214 C
3,227,173	1/1966	Bernstein	137/192
3,241,365	3/1966	Schroeder et al.	73/211
3,277,708	10/1966	Reynolds et al.	73/211
3,298,367	1/1967	Bergman	128/214 R
3,299,904	1/1967	Burke	137/315
3,316,935	5/1967	Kaiser et al.	137/595
3,321,970	5/1967	Walker, Sr. et al.	73/211
3,340,871	9/1967	Jellies	128/214
3,450,164	6/1969	Walker, Jr.	138/44
3,460,526	8/1969	McKirdy et al.	128/2.05
3,487,808	1/1970	Perkins	116/117
3,498,316	3/1970	Pinder et al.	137/595
3,550,619	12/1970	Halasz et al.	137/595
3,604,420	9/1971	Vallancourt	128/275
3,605,496	9/1971	Wenham	73/202
3,626,938	12/1971	Versaci	128/214 B
3,667,464	6/1972	Alligood, Jr.	128/214 C
3,677,248	7/1972	McPhee	128/227
3,690,318	9/1972	Gorsuch	128/214 E
3,756,233	9/1973	Goldowsky	128/214 C
3,759,098	9/1973	Logsdon et al.	73/205 R
3,785,378	1/1974	Stewart	128/214 C
3,796,245	3/1974	Wildensteiner	150/1
3,803,914	4/1974	Noiles	73/209
3,805,612	4/1974	Shiba	73/211
3,807,397	4/1974	Noiles	128/214 C
3,826,137	7/1974	Clarke	73/194 R
3,838,599	10/1974	Purtell	73/211
3,851,526	12/1974	Drexel	73/202
3,851,668	12/1974	Benjamin	137/625.3
3,931,818	1/1976	Goldowsky	128/214 C
3,938,539	2/1976	Strouth et al.	137/202
3,941,126	3/1976	Dietrich et al.	128/214 R
3,949,745	4/1976	Howell	128/214 C
3,963,024	6/1976	Goldowsky	128/214 C X
3,967,620	7/1976	Noiles	128/214 C
3,998,097	12/1976	Akashi et al.	73/211
4,043,332	8/1977	Metcalf	128/214 E
4,056,100	11/1977	Noiles	128/214 C
4,079,737	3/1978	Miller	128/214 R
4,099,527	7/1978	Howell	128/214 C
4,136,692	1/1979	Goldowsky	128/214 C
4,136,693	1/1979	Dyke	128/214 C
4,223,695	9/1980	Muetterties	128/214 G
4,256,103	3/1981	Mylrea	128/214 R

FOREIGN PATENT DOCUMENTS

817387	7/1959	United Kingdom	128/214 C
1182016	2/1970	United Kingdom	128/214 C

Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Kane, Dalsimer, Kane, Sullivan & Kurucz

[57] **ABSTRACT**

A medical fluid flow rate controller and method for its use are disclosed. The controller is particularly suited for intravenous liquid administration and comprises three chambers in series between the intravenous liquid source and the patient. The first and second chambers are movable vertically with respect to each other and

are gas phase pressure-equalized. Accordingly, the pressure differential available for flow from the first to the second chamber through the flow restrictor employed is known. Thus, the device may be precalibrated and marked with flow rates corresponding to different relative heights of the first chamber. Liquid entering the second chamber is pulled through a hydrophilic membrane into the third because the third operates at a lower pressure than the second. That configuration prevents the patient's movements from affecting the pre-set flow rate between the first and second chambers.

14 Claims, 13 Drawing Figures

Fig. 1.

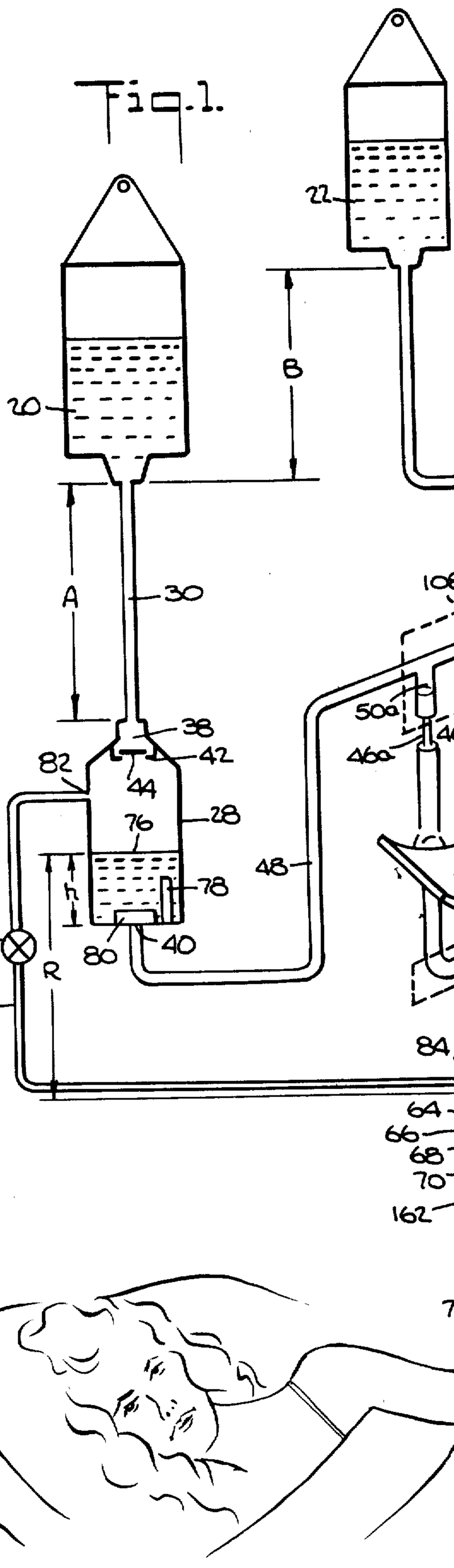
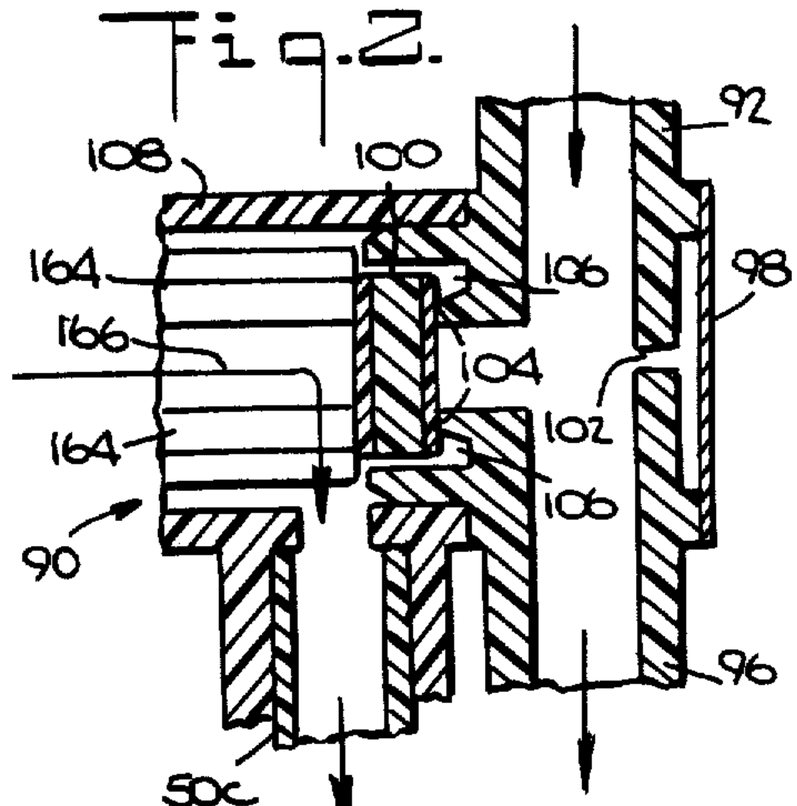

22
B
20
A
30
38
42
82
44
28
76
78
h
88
80
40
R
86
48
92
108
50c
506
46c
50a
466
46a
52
54
56
58
90
96
94
84
60
62
32
64
66
68
36
34
70
162
72
74
24
26
H

Fig. 2.


92
108
100
164
106
98
166
104
164
102
106
90
96
50c

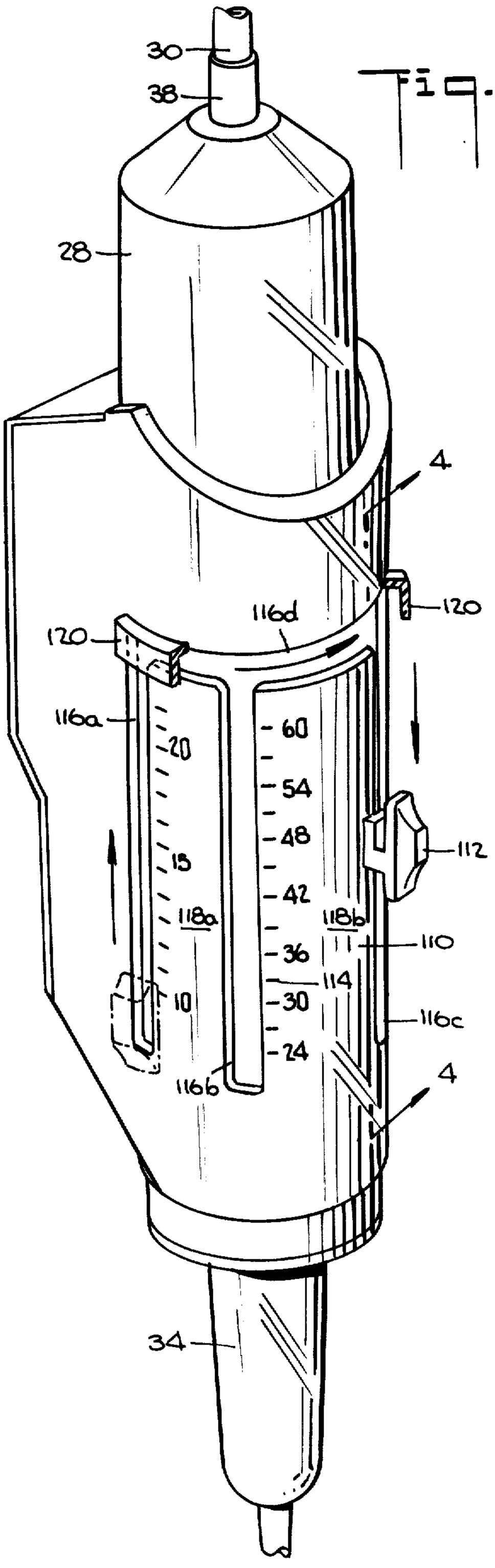


Fig. 3.

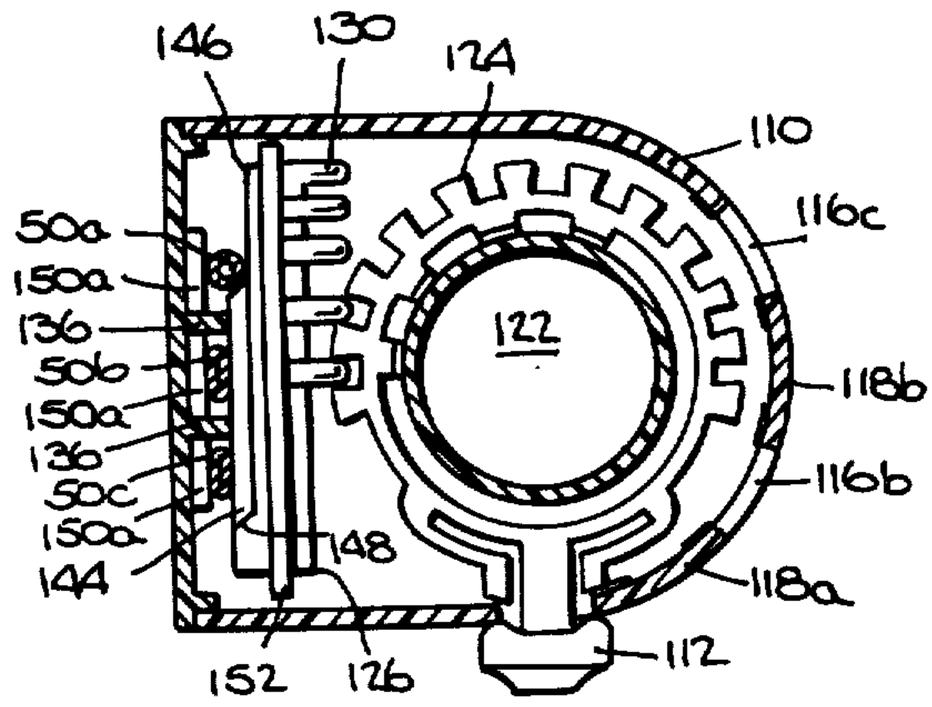


Fig. 8.

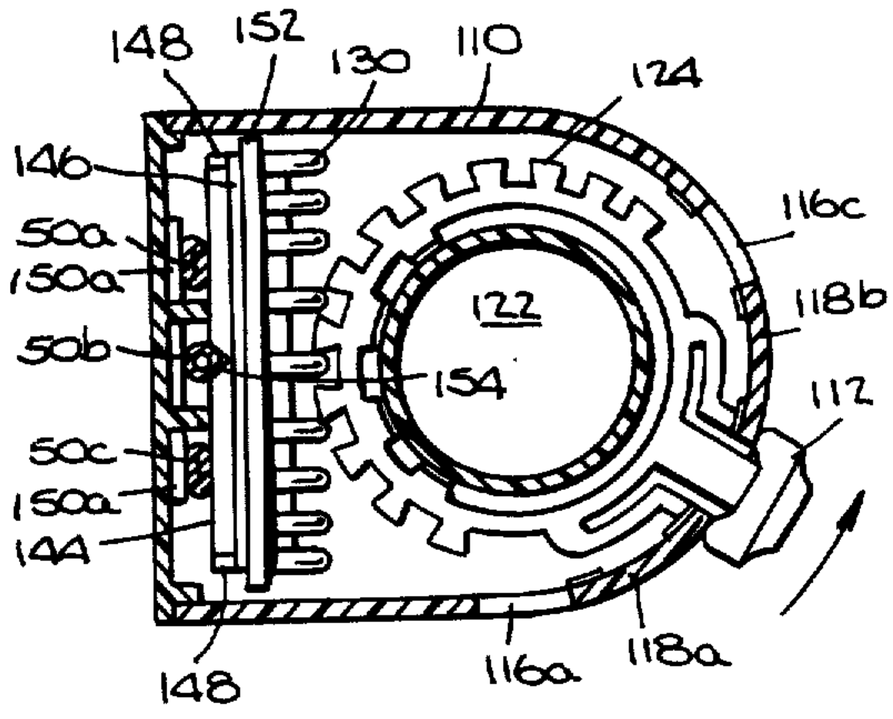


Fig. 9.

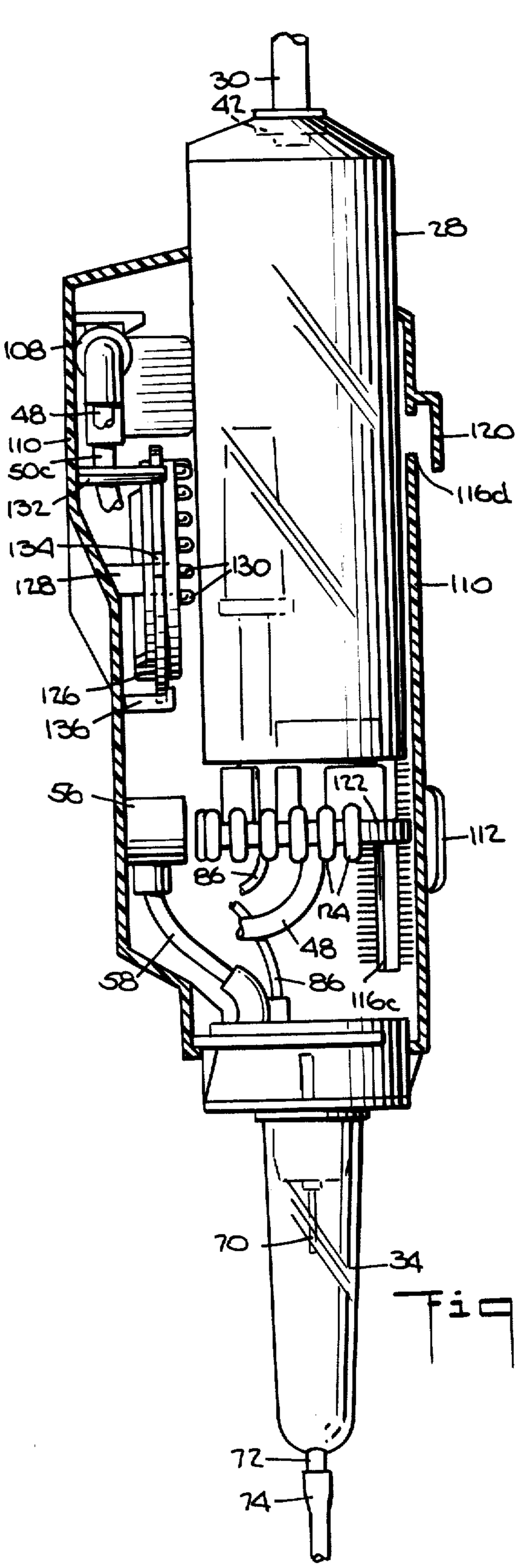

30
42
28
108
48
110
50c
132
134
128
130
120
116d
110
126
136
56
122
112
86
124
48
58
86
116c
70
34
72
74

Fig. 4.

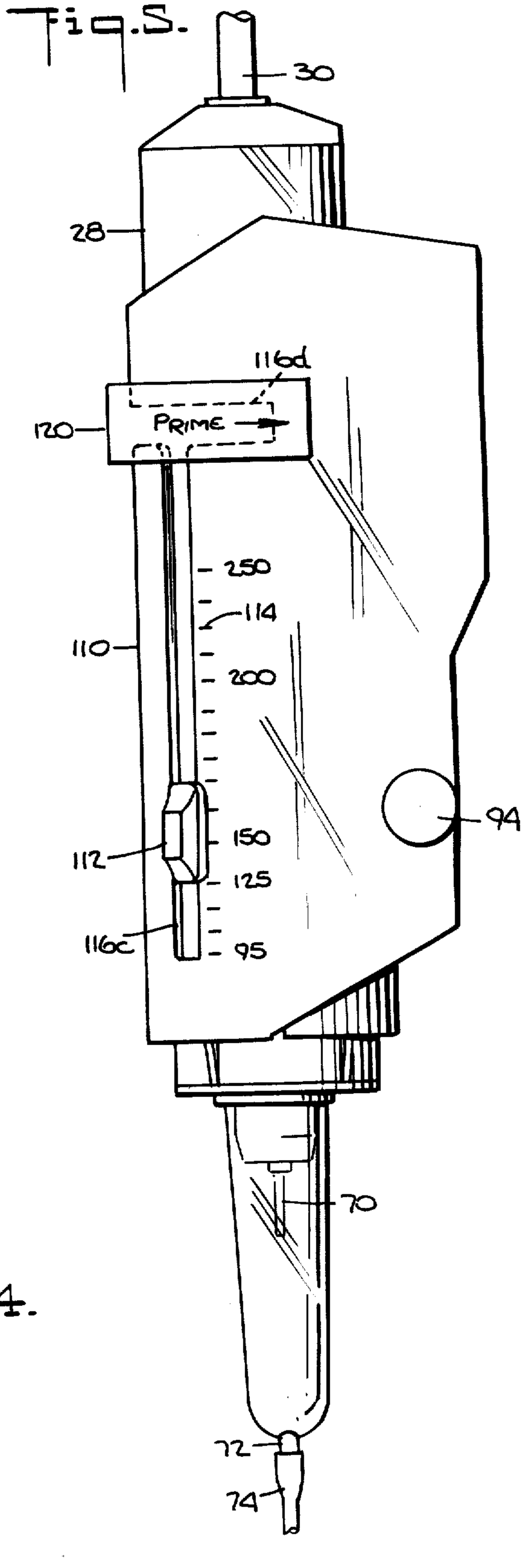
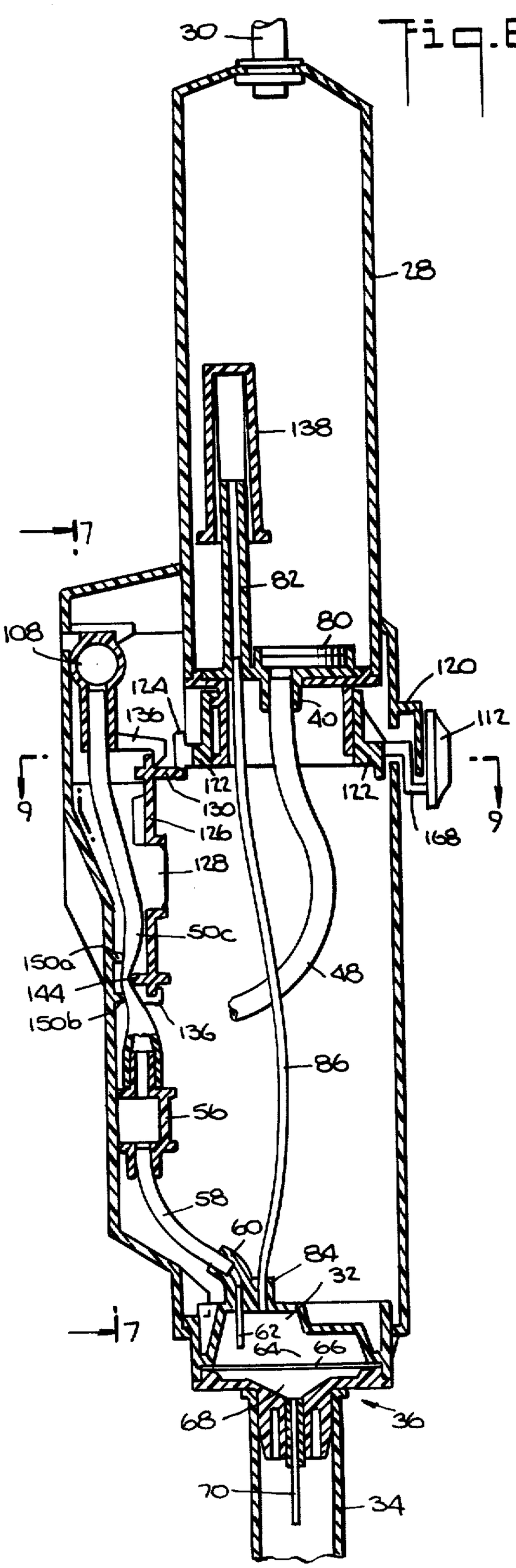

30
28
116d
120
PRIME
250
114
110
200
150
125
116c
95
94
70
72
74

Fig. 5.

Fig. 6.


30
28
138
82
80
108
120
124
136
40
112
122
122
130
126
168
128
50c
150a
144
150b
136
48
86
56
58
60
84
32
62
64
66
68
36
70
34
17
17
9
9

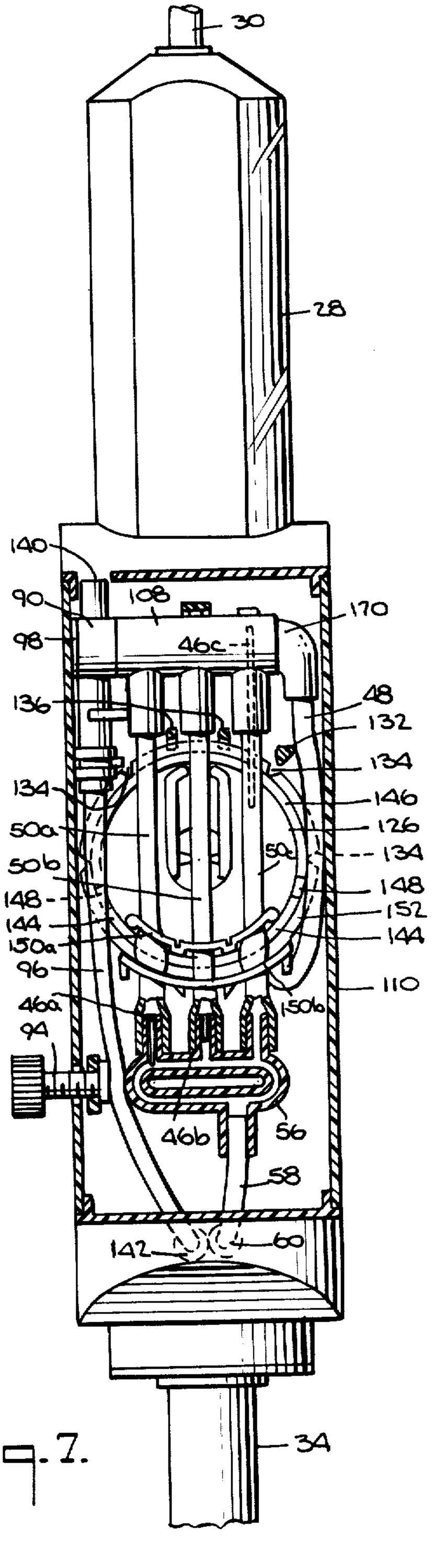

30
28
140
90
108
170
98
46c
136
48
132
134
134
146
126
50a
134
50b
50c
148
148
152
144
144
150a
110
96
46a
150b
94
46b
56
58
142
60
34

Fig. 7.

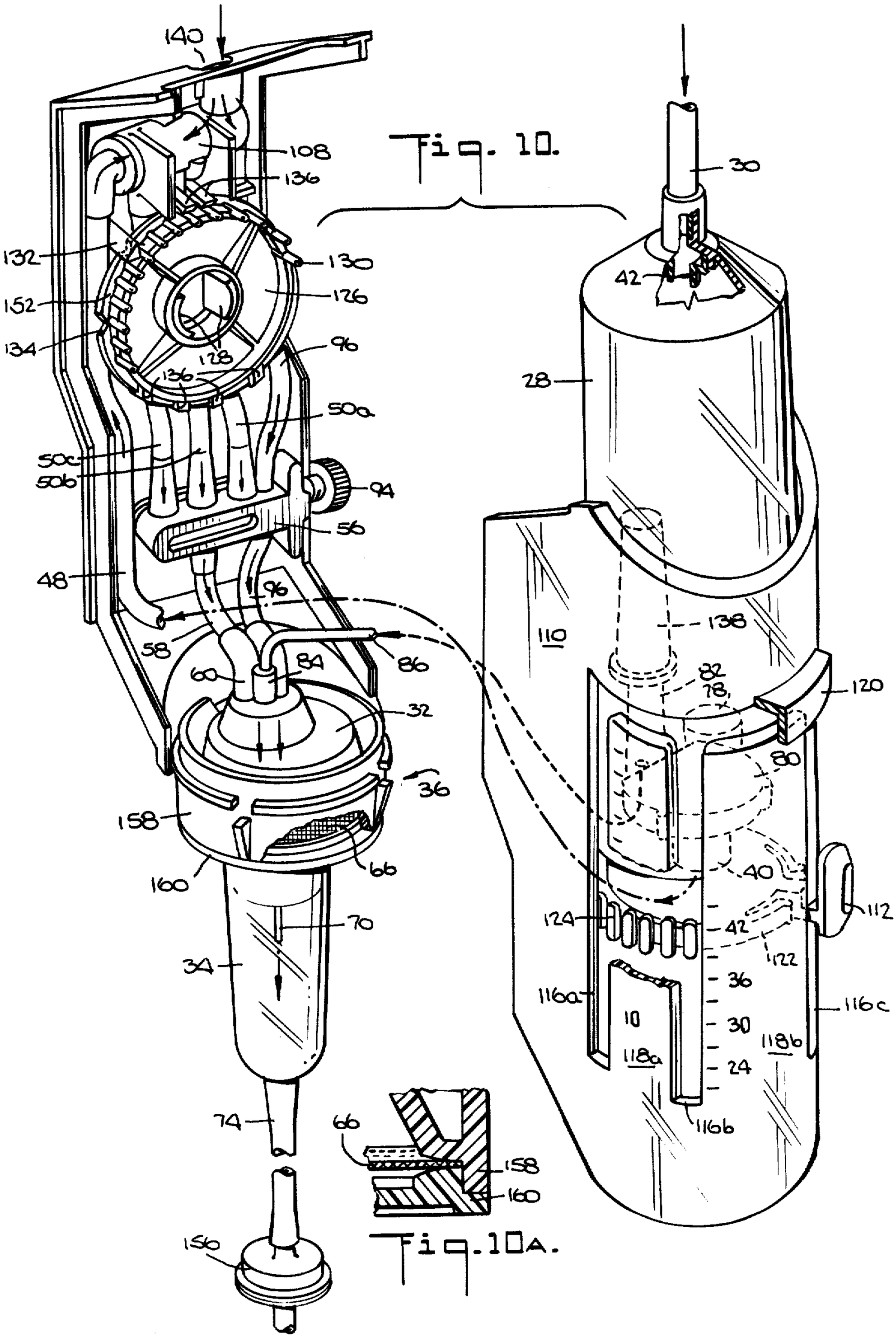


Fig. 10.

Fig. 10A.

Fig. 11.

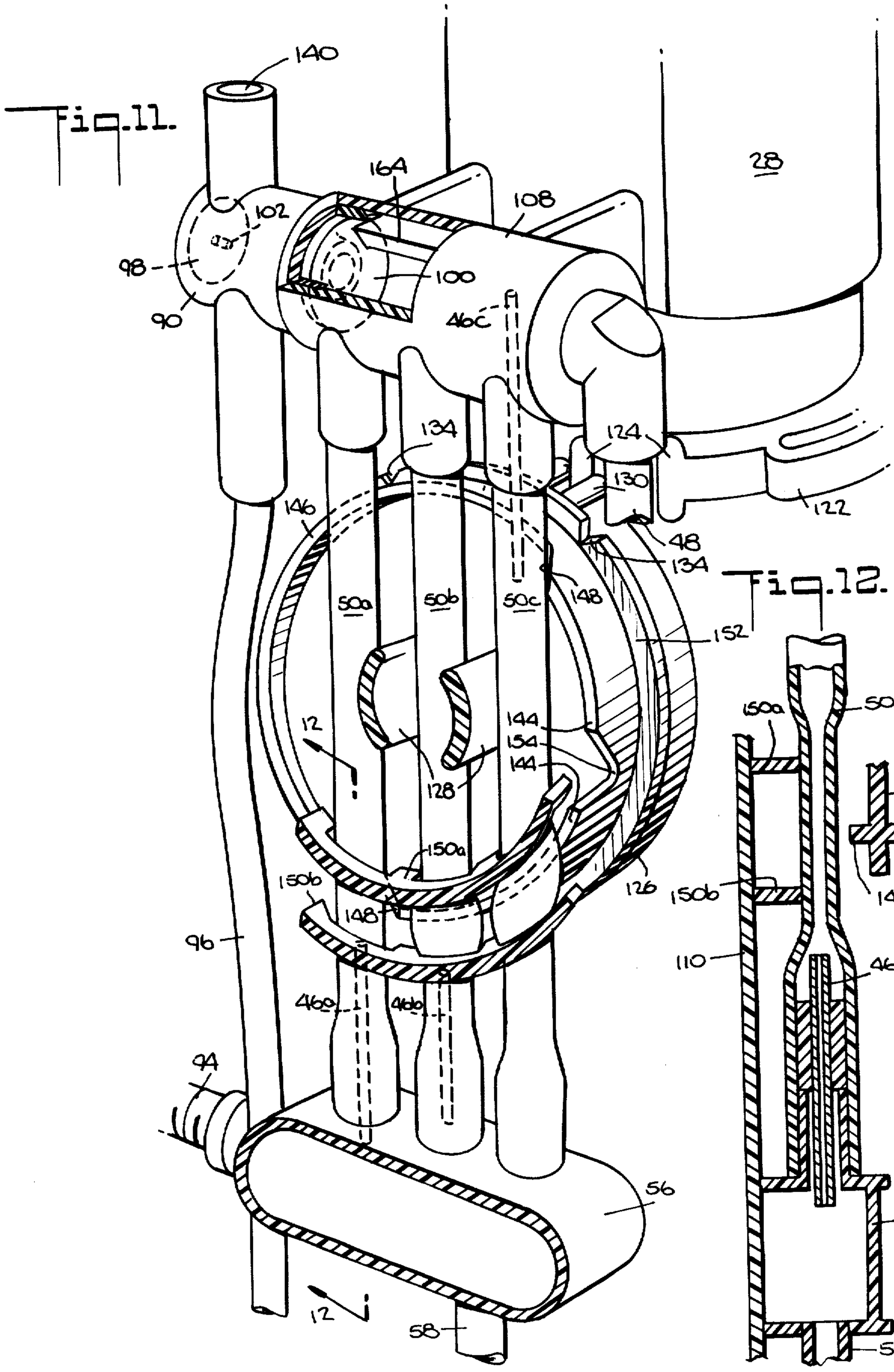

140
164
102
108
98
100
90
46c
F1
28
134
124
130
146
122
48
134
50a
50b
50c
148
152
12
144
154
144
128
150a
126
150b
148
96
46b
46b
94
56
58
12

Fig. 12.

150a
50a
126
150b
146
110
46a
56
58

MEDICAL FLUID FLOW RATE CONTROLLING DEVICE

BACKGROUND OF THE INVENTION

Numerous devices have been suggested for use in administering medical fluids to patients. In particular, there have been numerous attempts to design a reliable, accurate intravenous flow rate controller that is inexpensive enough to be disposable.

Desirably, such a device should handle a wide range of flow rates, be able to be quickly and accurately set to the desired flow rate, maintain the initially set rate, be easy to prime, handle a wide range of flows, reset automatically to the desired primary flow rate after any secondary fluid delivery ends, and stop fluid delivery before air enters the tube leading from the device to the patient.

If a device can do those things, chances for a medical emergency caused by excessive or insufficient flow of medication or by an air embolism from the procedure are reduced. Additionally, demands on nursing time are lessened because frequent readjustment to the initially set flow rate is not needed and hospital costs are lowered since a hospital need keep only one type of device in stock to handle both pediatric and adult patients (the typical flow rates are significantly different).

The classic intravenous metering set comprises a fluid supply container (commonly of 1 liter volume), a drip chamber, tubing from the bottom of the drip chamber to a needle in the patient, and a device to pinch the tubing to control the flow. Fluid from the supply container drips into the chamber through a standard size cannula at a rate determined by the internal cannula fluid pressure at the exit and the gas phase (head) pressure in the chamber (controlled indirectly by pinching the tubing).

The cannula is supposed to deliver a fixed number of drops per milliliter (typically 15, 20, or 60), and flow rate is set by pinching the tube to achieve a number of drops per unit time equivalent to the prescribed number of milliliters of medication per hour. However, cold-flow of the tubing material where pinched, which enlarges the cross-sectional flow path, and, in some systems, lowering of the fluid level in the supply container as fluid administration progresses may cause the flow rate to vary significantly from that initially set. Additionally, the flow rate usually will change with variations in the patient's venous pressure and vertical movement of the needle's point of entry.

Numerous attempts have been made to provide metering devices that are free from these problems. For example, U.S. Pat. No. 3,851,668 discloses a metering device having a flexible cylindrical housing and a ball movable therein. The housing has a plurality of vertical grooves of different lengths, widths, and depths on its inside wall. Fluid enters the housing above the ball and flows down through one or more of the grooves. The ball is moved vertically to change the total groove cross-sectional area available for flow.

U.S. Pat. Nos. 3,756,233 and 3,931,818 disclose two-chamber intravenous metering devices in which the fluid flow rate is controlled by varying the relative height of the chambers. The device of U.S. Pat. No. 3,931,818 makes use of tubing having a standard pressure drop to fluidly connect the two chambers and the chambers are gas phase pressure-equalized.

U.S. Pat. Nos. 3,207,372, 3,227,173, and 3,963,024 disclose devices having float check valves to prevent air

from entering the tubing leading from the device to the patient when the liquid in each device is exhausted. U.S. Pat. Nos. 3,967,620 and 4,056,100 disclose the use of hydrophilic material acting as membrane valves for the same purpose. Additionally, the devices of U.S. Pat. No. 3,963,024 utilize two fluid chambers that are gas phase pressure-equalized.

However, none of these patents provides a reliable, accurate, low-cost intravenous fluid flow rate controller that can maintain the initially set flow rate, is easy to prime, resets to the primary flow rate after any secondary fluid administration ends, and controls flow rate over a wide range of flows.

SUMMARY OF THE INVENTION

An invention providing a device meeting these requirements has now been discovered. Broadly, the apparatus of this invention comprises:

(a) a first chamber having a liquid inlet, a liquid outlet, and a gas phase connection, said liquid inlet designed to receive liquid from the supply of medical fluid;

(b) a second chamber having a liquid inlet, a liquid outlet, and a gas phase connection, said first chamber movable vertically with respect to the second chamber;

(c) gas phase pressure equalization means for equalizing the gas phase pressures in those chambers;

(d) first liquid connecting means fluidly connecting the liquid outlet of the first chamber to the liquid inlet of the second chamber, said first liquid connecting means having at least one flow restrictor in the fluid flow path through which a known quantity of liquid flows when a given differential pressure exists across it;

(e) a third chamber having a liquid outlet from which liquid passes to the patient and a liquid inlet for receiving liquid from the second chamber; and

(f) second liquid connecting means fluidly connecting the liquid outlet of the second chamber to the liquid inlet of the third chamber, said second liquid connecting means having a membrane valve in the flow path which when wet passes liquid but not gas under normal operating conditions.

In other embodiments, the one or more flow restrictors are cannulae, the second and third chambers are in the same housing, the flow restrictor provides the only significant pressure drop in the fluid flow path from the first chamber to the second chamber, indicia on the device correspond to different vertical heights of the first chamber and different flow rates of liquid through the flow restrictor, and the device contains means to control the flow of secondary fluid, halt temporarily the flow of primary fluid, and restart the primary flow at its previously set rate after secondary flow ends.

Another aspect of the invention relates to methods of controlling the flow of medical fluids to patients utilizing various embodiments of the device.

BRIEF DESCRIPTION OF THE DRAWINGS

To facilitate further description of the invention, the following drawings are provided in which:

FIG. **1** is a schematic of the fluid flow scheme in a preferred device according to the present invention used to administer medical liquid intravenously to a patient;

FIG. **2** is an enlarged detail view of a valve assembly used in a preferred device utilizing the flow scheme of FIG. **1**, said valve assembly used when liquid from a

secondary liquid source is to be administered to a patient;

FIG. 3 is a perspective view of the same preferred device utilizing the flow scheme of FIG. 1 whose valve assembly is shown in FIG. 2;

FIG. 4 is a side sectional view of the device taken along line 4—4 of FIG. 3;

FIG. 5 is a view of the device from the side opposite that of FIG. 4;

FIG. 6 is a side sectional view of the device;

FIG. 7 is a rear view of the device taken along line 7—7 of FIG. 6;

FIG. 8 is an overhead sectional view of the device similar to that of FIG. 9;

FIG. 9 is an overhead sectional view of the device taken along line 9—9 of FIG. 6;

FIG. 10 is an exploded view of the device, with a detail view (FIG. 10A) showing how the membrane filter is held in place;

FIG. 11 is an enlarged perspective detail view of the back of the device showing the three cannulae used therein in their respective tubing; and

FIG. 12 is a side sectional view taken along line 12—12 of FIG. 11.

It should be understood that these drawings are provided for illustrative purposes only and should not be construed to limit the scope of the invention. It should also be understood that for the sake of clarity details shown in one view may not be shown in other views. For example, details of most of the flexible tubing inside the device of FIGS. 2–12 are omitted from one or more of those drawings.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 is a schematic of a preferred device embodying the present invention. The flow rates of primary intravenous fluid from supply 20 and secondary intravenous fluid from supply 22 to needle 26 in patient's arm 24 are controlled by the new device. Broadly, primary fluid flows from supply 20 into first chamber 28, into one of three cannulae 46, out of dropping needle 62 in second chamber 62, through membrane valve 66, into third chamber 34, and then to the patient. The secondary fluid flows from supply 22 into valve 90 in which the flow is split into two parallel but unequal streams, which are through the cannula 46 that was being used for the primary fluid and through line 96. The two parallel flows rejoin and then, as for the primary fluid, pass through dropping needle 62, membrane valve 66, third chamber 34, and into the patient. Administration of secondary fluid temporarily halts the flow of primary fluid; when the secondary supply is exhausted primary flow restarts at its originally set flow rate.

More specifically, primary fluid leaves supply 20 through tubing 30 and enters first chamber 28 through inlet 38 containing check valve 42. Movable valve member 44 can move up and down, down to admit primary liquid and up to block the flow of fluid from first chamber 28 back into tubing 30. Liquid 76 leaves first chamber 28 through hydrophilic filter 80 at outlet 40, passes through tubing 48 and into header 108 having three branches 50. Each branch 50 has a cannula 46 of a different size, and slide valve 52 contains notch 54.

In FIG. 1, notch 54 is disposed around and does not pinch the flexible tubing for branch 50*b*, while branches 50*a* and 50*c* are pinched shut between the back edge of slide valve 52 and another member (not shown). Accordingly, fluid entering header 108 passes through cannula 46*b* but not through cannulae 46*a* or 46*c*. If slide valve 52 were moved so that notch 54 were around the tubing for branch 50*a* or 50*c*, fluid would flow, respectively, through cannula 46*a* and 46*c* only.

The three branches join at collection header 56, from which the fluid flows through tubing 58 into second chamber 32 via inlet 60 having dropping needle 62, from which the fluid falls in the form of drops onto membrane filter 66 at outlet 64. Liquid passes through membrane filter 66 into third chamber 34 via inlet 68 leading to dropping needle 70. The liquid leaves third chamber 34 via outlet 72 from a small pool of fluid 162 at the bottom of the chamber and flows through tubing 74 into needle 26 in patient's arm 24. Second chamber 32 and third chamber 34 are located in the same housing 36 and are separated by membrane valve 66.

The gas phase in first chamber 28 (above liquid 76) and the gas phase in second chamber 32 (which chamber contains essentially only gas) are pressure equalized through tubing 88, which connects outlets 82 and 84 of the two chambers. Priming valve 88 in tubing 86 is normally open.

Before the device is used for the first time, the entire device, including the three chambers and connecting tubing, contains only air. To use it, priming valve 88 is closed, slide valve 52 is moved so that all three branches can pass liquid, and primary supply 20 is fluidly connected to tubing 30 so that liquid flows from supply 20 through tubing 30, through inlet 38 and valve 42, and to the bottom of first chamber 28.

As air leaves the first chamber through hydrophobic membrane valve 78, the liquid rises past the top of hydrophilic membrane valve 80 and flows through outlet 40 into tubing 48 (hydrophobic valve 78 is higher than hydrophilic valve 80). The liquid then flows into header 108 and through all three branches 50 until the three cannulae 46 are reached. Liquid temporarily stops flowing out of first chamber 28 because the cannulae provide the only significant flow restriction (or pressure drop) from outlet 40 to inlet 60. That is, additional pressure is required to force the liquid through the cannulae. Thus, since the liquid flowing into first chamber 28 from supply 20 cannot leave, the level of liquid 76 starts to rise and the liquid forces additional air out of the first chamber 28 through hydrophobic membrane valve 78. The gas phase pressure has to this point remained essentially at atmospheric.

When the liquid rises sufficiently to cover membrane 78, air can no longer leave and first chamber 28 starts to pressurize. Pressurization caused by fluid entering from supply 20 continues until the pressure of the gas compressed within first chamber 28 reaches the hydrostatic pressure on the fluid entering (at inlet 38).

Sometime during or at the end of pressurization, the pressure required to force the liquid through cannulae 46 is reached and liquid flow through them commences. The liquid from them passes into header 56, tubing 58, and dropping needle 62, thereby purging air through dry hydrophilic membrane valve 66 and out needle 26 (which, of course, has not yet been placed in the patient). When liquid finally wets membrane valve 66 sufficiently, air no longer can pass through it and the air in second chamber 32 becomes trapped therein (valve 88 is still closed and membrane valve 66 will not pass air). The liquid passes through membrane valve 66 into inlet 68 in third chamber 34, through dropping needle 70, through outlet 72 into tubing 74, and out needle 26.

Reference numeral **162** denotes the liquid hold-up at the bottom of the third chamber **34**.

Fluid continues to flow at a high rate into first chamber **28** and out needle **26** until slide valve **52** is moved out of the priming position and notch **54** engages the tubing for one of the three branches **50**. Then, as described above, liquid flows through only one of the three cannulae **46**. Additionally, at the end of the priming procedure valve **88** is opened, allowing the gas pressure in first and second chambers **28** and **32** to equalize.

The height of liquid in supply **20** typically varies from approximately 16 inches (406 mm) for a full 1-liter IV bag down to 0 inches when empty. Tubing **30** is approximately 6 inches (152 mm) long (dimension A). Thus, the hydrostatic head on fluid entering at inlet **38** is typically between approximately 6 and 22 inches (152 and 559 mm, respectively). For the device of FIGS. **2** to **12**, this difference in head causes the level of fluid **76** above membrane **78** to vary from 0.125 to 0.185 inches (3.2 to 4.7 mm). Also, for the same device, dimension h (the height of fluid above outlet **40**) is approximately 0.375 inches (9.5 mm) and because first chamber **28** is movable vertically with respect to second chamber **32**, vertical dimension R (the top of fluid **76** to the end of dropping needle **62**) varies from approximately 1.75 to 4.5 inches (45 to 114 mm).

First and second chambers **28** and **32** are gas phase pressure-equalized by tubing **86**, thus, a pressure loss equal to hydrostatic head R (1.75 to 4.5 inches—45 to 114 mm—of liquid) is what is available to move the liquid from first chamber **28** to the end of dropping needle **62**. The device is designed so that essentially all of the pressure loss occurs in whichever cannula is selected, that is, the cannula provides the only significant pressure drop in the fluid path from outlet **40** to the end of dropping needle **62**. Accordingly, for each cannula, a specific value of R causes a specific predeterminable flow rate of liquid and, therefore, the device can be premarked with indicia at different relative first chamber heights corresponding to those flow rates.

Those premarked flow rates will be correct within the accuracy required for liquids not varying significantly in specific gravity or viscosity from that of the liquid used to calibrate and premark the device (e.g., plus or minus 10% in viscosity). For example, if the device is premarked with flow rates for saline solution, having a viscosity at room temperature of about 1 cp, the device may be used with fluids having viscosities up to 1.1 cp without significant error. Of course, the device may be calibrated and premarked for higher viscosity fluids.

The gas phase pressure in third chamber **34** is below atmospheric. It is equal to atmospheric pressure minus the pressure equal to the height of fluid from the top of fluid **162** to the discharge end of needle **26** (dimension H) plus the venous pressure. That typically is equal to a vacuum of approximately 30 inches (762 mm) of liquid (H is approximately 36 inches—914 mm—and venous pressure is typically 5 to 6 inches—127 to 152 mm).

The gas phase pressure in second chamber **32** is above atmospheric and is the same as the gas phase pressure in first chamber **28** or between 6 inches and 22 inches (152 and 559 mm) of liquid gauge. Thus, the pressure differential drawing liquid that falls from dropping needle **62** onto membrane **66** into third chamber **34** is from 36 (6 plus 30) to 52 (22 plus 30) inches (914 to 1321 mm) of liquid. Accordingly, the flow rate of liquid from supply **20** through dropping needle **70** is independent of the patient's raising or lowering the needle's point of entry (assuming it is not raised sufficiently to decrease the driving force on the liquid passing through membrane **66** from second chamber **32** to zero or less).

If secondary liquid is to be administered, the discharge of secondary supply **22** is placed at a level higher than the discharge of primary supply **20** (dimension B), typically 9 inches (229 mm) higher. Tubing **92** from supply **22** is connected to valve assembly **90**, and assembly **90** is connected to header **108** and to tubing **58** by tubing **96**. A small amount of secondary fluid then flows along tubing **48** to header **108** and forces liquid back into first chamber **28** because of the higher hydrostatic head on liquid leaving supply **22**. That raises the level of liquid in first chamber **28**, which further pressurizes the gas therein. That, in turn, causes inlet valve member **44** to move up within valve **42** and temporarily halt the flow of primary fluid into first chamber **28**. Since priming valve **88** is open, the gas phase pressure in second chamber **32** also rises.

Secondary fluid forced into header **108** also flows through whichever branch **50** was being used to meter the primary fluid. The major flow of secondary fluid, however, is through tubing **96**. The minor flow of secondary fluid through one of the branches **50**, cannula **46**, header **56**, and tubing **58** mixes with the major flow through tubing **96**. The combined flow enters second chamber **32** through inlet **60**, flows out of dropping needle **62**, out outlet **64**, through hydrophilic membrane valve **66**, into third chamber **34** through inlet **68**, through dropping needle **70**, and to the patient through tubing **74** and needle **26**. The flow rate of secondary fluid out of dropping needle **70** in third chamber **34** is adjusted by valve **94**.

Typically, secondary fluid is administered at comparatively high flow rates and in volumes less than 100 cc. After secondary supply **22** is exhausted, the level of liquid in tubing **92** falls, thereby decreasing the gas phase pressure in first chamber **28**. At some point, the liquid in tubing **92** falls to a level such that the hydrostatic pressure on primary fluid entering first chamber **28** at inlet **38** is greater than the gas phase pressure. When this happens, valve member **44** moves down and the flow of primary fluid into first chamber **28** resumes. Because neither the relative height of the first and second chambers nor slide valve **52** had to be moved to administer secondary fluid, the primary fluid resumes its flow out of first chamber **28** and into the patient at the rate set before administration of the secondary fluid commenced.

FIG. **2** is a detailed view, showing valve assembly **90** in a device embodying the principles of FIG. **1**. Valve **100** in valve assembly **90** comprises three layers: a central compressible foam rubber disc and two matching silicone rubber discs, one on either side of the foam rubber. In FIG. **2** the foam core of valve **100** is fully expanded between support ribs **164** of header **108** and valve seat **104**. (Upper rib **164** is also shown in FIG. **11**.) When primary fluid flows it enters heater **108** and passes next to lower rib **164** into one of three branches, as indicated by arrow **166**. The right silicone rubber disc of valve **100** is seated on valve seat **104**, thus preventing primary fluid from entering tubing **92** or **96**. That ensures that all the primary fluid leaving primary supply **20** and entering header **108** passes through the cannula selected (in FIG. **2**, branch **50***c* and cannula **46***c*).

When secondary fluid flows into valve assembly **90** via tubing **92**, the major part of the flow passes directly into tubing **96** and to the patient, as explained above. All of the air in tubing **92** and **96** passes through opening **102** and out of the device through hydrophobic membrane valve **98**. The higher hydrostatic head on the secondary liquid to the right of valve **100** pushes the right silicone rubber disc of valve **100** to the left, thereby temporarily compressing the central foam rubber core and allowing secondary fluid to flow through passageway **106** into header **108**. As explained above, this minor flow of secondary fluid causes the flow of primary fluid into first chamber **28** to stop temporarily by closing inlet valve **42**. Additionally, some of this secondary fluid passing into header **108** flows through whichever cannula was being used for the primary fluid (in this case, cannula **46***c*).

When the hydrostatic head on the secondary fluid to the right of valve **100** is no longer sufficient to keep valve **100** open, the flow of secondary fluid into header **108** stops, thereby removing the hydrostatic back-pressure on the liquid at the bottom of first chamber **28** caused by the secondary fluid. There is then no extra liquid phase pressure to maintain the additional compression on the gas in first chamber **28**. The gas expands and its pressure falls until inlet valve **42** reopens and primary liquid flow resumes, as explained above. Tubing **96** remains filled with secondary liquid.

FIG. **3** is a perspective view of the preferred device containing valve assembly **90** of FIG. **2** and constructed in accordance with the schematic of FIG. **1**. First chamber **28**, having tubing **30** from primary supply **20** (not shown) connected to inlet **38**, is moved up and down within housing **110** by button **112**, which moves within slot **116**. The slot comprises three vertical portions, **116***a, b,* and *c,* and one horizontal portion, **116***d*. Because of the configuration of the slot, housing portions **118***a* and *b* are connected to the rest of housing **110** at only their bottom ends. Thus, shield **120** (only a portion of which is shown) is provided to prevent excessive outward movement of those portions. Shield **120** is constructed so that arm **168** of button **112** (FIG. **6**) is free to slide under it when the button is in slot portion **116***d*.

Each slot portion **116***a, b,* and *c* corresponds to selection of one of the three cannulae, as will be described below. Button **112** in phantom line corresponds to selection of branch **50***a* with cannula **46***a*. To change, for example, to cannula **46***c*, which is used for the highest range of flow rates, button **112** is moved up in slot portion **116***a,* pushed to the right in slot portion **116***d,* and then pushed down into slot portion **116***c* to the desired level. In this device, dropping needle **62** in second chamber **32** is held stationary in housing **110** and first chamber **28** is movable vertically within the housing to vary dimension R (FIG. **1**), thereby to set the flow rate. Indicia **114** to the sides of slot portions **116***a, b,* and *c* are in milliliters per hour and correspond to the particular cannula and height R chosen.

FIG. **4** is a sectional view of the device taken along line **4—4** of FIG. **3**. Button **112** is connected to lever gear **122** having teeth **124**. The gear is rotatably connected to the bottom of first chamber **28**. When button **112** is pushed up as high as it will go, first chamber **28** is pushed to its highest and teeth **124** mesh with teeth **130** on horseshoe gear **126**, which is rotatably mounted on mounts **128** connected to the back wall of housing **110**.

Detent **132** rides on the rim of horseshoe gear **126** (see also FIG. **10**), which rim has four notches **134**. Three notches are positioned to mate with detent **132** when button **112** is in one of the slot portions **116***a, b,* or *c*. The fourth notch **134** mates with detent **132** when button **112** is in horizontal slot portion **116***d* and is moved past the highest flow range, a position denominated "Prime" on housing **110** (see FIG. **5**). Detent **132** and the notches cooperate to prevent movement of horseshoe gear **126** when first chamber **28** moves down in housing **110**, which unmeshes teeth **124** (on lever gear **122**) and teeth **30** (on gear **126**).

Retaining clips **136**, mounted on the back wall of housing **110**, keep horseshoe gear **126** from slipping off of or tilting on mounts **128**. Also shown in FIG. **4** are dropping needle **70** in third chamber **34** and tubing **74** connected to outlet **72**.

Various fluid connecting means (or tubing) are shown cut-away for clarity. Tubing **48** carries primary liquid from the bottom of first chamber **28** to header **108**, mounted on the rear wall of housing **110**. Tubing **86**, for gas phase pressure equalization, runs from first chamber **28** to the bottom of housing **110**, where second chamber **32** (not shown) and third chamber **34** are located. The three branch lines **50** (only one of which, **50***c,* is shown) run from header **108** down to collection header **56** and tubing **58** runs from header **56** to the inlet of the second chamber.

FIG. **5** shows the outside of the device opposite the side of FIG. **4**. Shield **120**, which follows slot portion **116***d,* is shown. Button **112** is in slot portion **116***c,* allowing metering of primary flows in the 95 to 250 ml/h range. Valve **94** allows flow rate control of the secondary fluid.

FIG. **6** is a view of the same side of the device as in FIG. **4** but with the entire device in section. Chamber **28** has been raised to its highest position by button **112** and teeth **124** and **130** of gears **122** and **126** are meshed. Arm **168** connects button **112** to lever gear **122**. Tubing **86**, which equalizes the gas phase pressures in first and second chambers **28** and **32**, runs from gas phase connection (or riser) **82** to gas phase connection **84**. Although the liquid level in chamber **28** (dimension h in FIG. **1**) is only approximately 0.375 inches (9.5 mm) for this device and the riser is approximately 1.4 inches (36 mm) high, cap **138** is provided to prevent liquid entering first chamber **28** via tubing **30** from going into riser **82** and tubing **86**. Liquid leaving first chamber **28** passes through hydrophilic membrane valve **80** and outlet **40** before entering tubing **48** (only a portion of which is shown) to go to header **108**.

Whereas in FIGS. **3**, **4**, and **5** the device is shown with button **112** in slot portion **116***c,* that is, the device is set for the highest flow range (cannula **46***c* is selected), in FIG. **6** button **112** is in slot portion **116***b,* that is, the middle flow range (cannula **46***b*) is selected. Accordingly, as in FIG. **1**, branch tubing for the other two cannulae must be pinched so that liquid flowing from header **108** to header **56** passes through cannula **46***b* only.

FIG. **6** shows how this pinching is accomplished. Back rim raised portion **144** of horseshoe gear **126** pushes a section of branch tubing **50***c* against upper and lower compression bars **150***a* and *b,* which are mounted on the rear wall of housing **110**. That pinches tubing **50***c* sufficiently to prevent fluid flow through it. Another portion of back rim raised portion **144** pinches tubing **50***a* (not shown) with the same result. Thus, only tubing

50*b* (not shown) remains open. Top and bottom retaining clips **136** ensure that back rim raised portion **144** sufficiently pushes tubing **50***a* and *c* against compression bars **150**.

Liquid flowing from header **108** to collection header **56** leaves the latter through tubing **58**, enters second chamber **32** at inlet **60**, and flows through dropping needle **62**. Liquid from needle **62** drops onto and flows through hydrophilic membrane valve **66** to inlet **68** of third chamber **34**. Liquid falling into inlet **68** flows to the bottom of the inlet area and then through dropping needle **70** into the main plenum of third chamber **34**. Second and third chambers **32** and **34** are located in T-shaped housing **36** and are separated by membrane valve **66**: above membrane **66** is outlet **64** of second chamber **32** and below membrane **66** is inlet **68** of third chamber **34**.

FIG. **7** is a rear view of the device. Tubing **48** from the bottom of first chamber **28** passes up the right inside of the device to elbow **170**, which leads into header **108**. Branch tubing sections **50***a, b,* and *c* run from header **108** to collection header **56** and tubing **58** carries liquid from the latter to second chamber inlet **60**. Each branch **50** has a cannula **46** in it. As in FIG. **6**, back rim raised portion **144** is compressing branch tubing **5***a* and *c* against compression bars **150***a* and *b* to prevent flow through them. The sides of notch **154**, centrally located in raised portion **144** (not shown—see FIG. **11**), bracket but do not compress tubing **50***b* in the region between compression bars **150**. That is why tubing **50***b* is not also compressed by raised portion **144**.

Cannula **46***a* and *b* are located close to header **56**; cannula **46***c* is located with its upper end close to the inside top of header **108** to provide a path for air in header **108** to leave when the device is primed.

The back rim of horseshoe gear **126** has raised portion **144** and lower portion **146**, with two transition sloped surfaces **148**. Shown in this view are the four notches **134** that mate with detent **132** and the end of the detent connected to the rear wall. Also visible are the ends of the two upper retaining clips **136**, which are connected to the rear wall.

Secondary fluid supply **22** (not shown) is connected to the device by inserting a needle at the end of connecting tubing **92** (not shown—see FIG. **1**) into elastomeric stopple **140**. The secondary fluid then flows directly into valve assembly **90**. The details of the construction and operation of valve assembly **90** are described above in connection with FIG. **2**. The major portion of secondary liquid flowing through valve assembly **90** goes into tubing **96**, which meets with tubing **58** at header **142** atop second chamber **32** (not shown). The minor portion of the flow goes through tubing **58**, and the combined flow at header **142** goes into second chamber **32** through dropping needle **62** (not shown—see FIG. **6**). Valve **94** is a screw-compression type. As valve **94** is turned clockwise to decrease the secondary fluid flow rate, tubing **96** is pinched between the end of the screw and the left end of collection header **56**. Counter-clockwise rotation increases the flow rate.

FIGS. **8** and **9** are top sectional views taken along line **9—9** of FIG. **6**. FIG. **9** shows the device in the same configuration as in FIG. **6**, that is, set to the middle flow range. FIG. **8** shows the device set to the lowest flow range. In both views (FIGS. **8** and **9**), teeth **124** of lever gear **122** are meshed with teeth **130** of horseshoe gear **126** and branch tubing sections **50***a, b,* and *c* are seen to be between gear **126** and upper compression bar **150***a* (the lower compression bar is not visible).

In FIG. **8** button **112** is set to the lowest flow range (as shown in phantom line in FIG. **3**). Tubing **50***b* and *c* are both clamped shut between back rim raised portion **144** and compression bars **150**. One of the inclined transition surfaces **148** (between back rim raised and lower portions **144** and **146**) lies next to tubing **50***a*, which remains open, thereby allowing primary flow through cannula **46***a* only.

When button **112** is moved within slot portion **116***d* (FIG. **3**) to the position shown in FIG. **9**, gear **122** rotates counter-clockwise causing horseshoe gear **126** to rotate counter-clockwise when viewed from the front. That moves notch **154** around tubing **50***b* and causes the rest of back rim raised portion **144** to clamp shut branch tubing **50***a* and *c*, as in FIG. **9**. Button **112** is now positioned over slot portion **116***b* and may be moved vertically therein.

FIG. **10** is an exploded perspective view of the device showing the front of housing **110** and first chamber **28** broken away from the rear of housing **110** and second and third chambers **32** and **34**. Valve **42** admits primary liquid from tubing **30** into first chamber **28**. Button **112** is in slot portion **116***c*, that is, the device is set to the highest flow range. Shown in phantom line are hydrophobic membrane valve **78** (which allows air to leave the chamber during priming), hydrophilic membrane valve **80** (through which primary liquid from first chamber **28** passes via tubing **48** to header **108**), riser **82** with cap **138** (which riser is connected to second chamber **32** by gas phase pressure equalization tubing **86**), and lever gear **122**.

On the rear section of housing **110**, the six retaining clips **136** holding horseshoe gear **126** on mounts **128** are visible, two clips at the top of the gear and four clips at the bottom. Detent **132** and one of the four grooves in rim **152** on gear **126** are cooperating to prevent accidental rotation of gear **126**. Tubing **58** (from collection header **56**), tubing **86** (from riser **82**), and tubing **96** (for carrying secondary fluid admitted through stopple **140**) meet at the top of the smaller, raised portion of second chamber **32**.

Hydrophilic membrane valve **66** separates second and third chambers **32** and **34**. Liquid from the latter flows to the patient through tubing **74**, which has check valve **156** in the flow path. FIG. **10A** shows that membrane **66** is mounted between sidewall **158** and horizontal portion **160** of housing **36**.

FIG. **11** is a rear perspective view of horseshoe gear **126**, the headers, and associated tubing. In this view the device is set to the lowest flow range: gear **126** has been rotated clockwise (when viewed from the front) as far as possible. Thus, one part of back rim raised portion **144** is compressing tubing **50***b* and *c* against compression bars **150***a* and *b*, thereby preventing flow through middle and high range cannulae **46***b* and *c*, but back rim lower portion **146** is not pinching tubing **50***a*, thereby allowing flow through low flow range cannula **46***a*.

First chamber **28** is at its highest and teeth **124** and **130** of lever gear **122** and horseshoe gear **126** are meshed. Valve **100** lies between ribs **164** and valve assembly **90** and air exit port **102** and hydrophobic membrane valve **98** are visible (see FIG. **2**). Secondary tubing **96** is positioned between the left end of collection header **56** and the end of the screw of valve **94**.

FIG. **12** is a sectional view taken along line **12—12** of FIG. **11** and shows that with the horseshoe gear in the

position shown in FIG. **11**, back rim lower portion **146** does not force branch tubing **50***a* against compression bars **150***a* and *b*. Therefore, tubing **50***a* remains open and all the liquid flowing from header **108** to collection header **56** must pass through cannula **46***a*.

The procedure for priming and using the device of FIGS. **1–12** follows the scheme set forth above in discussing FIG. **1**. With the device of FIGS. **2–12**, button **112** is moved up to slot portion **116***d* (FIG. **3**) and the button is moved to the "Prime" position (FIG. **5**). That causes horseshoe gear **126** to rotate counterclockwise (when viewed from the front) as far as possible so that the raised portion **144** of the rear rim does not contact any of the three branches **50**. Thus, liquid flows through all three. Also, when button **112** is moved to "Prime," a tab at the bottom of and on lever gear **122** is brought around to bend over and thereby crimp and close off pressure equalization tubing **86** near where the tubing exits from first chamber **28** (see FIG. **6**, although the tab is not shown). Thus, that tab performs the function of valve **88** in FIG. **1**.

Dimensions for the device of FIGS. **2–12** that have been found to be satisfactory are as follows (all values are approximate). First chamber **28** is 1.5 inches (38 mm) in diameter by 4.3 inches (109 mm) long (straight-side). Housing **110** from its top to the bottom of third chamber **34** (FIG. **4**) is 8.6 inches (216 mm) long and 2.5 inches (64 mm) at its widest (not including shield **120**). The other dimensions may be determined by consulting FIGS. **4–9** since they are essentially to scale. Cannula **46***a*, for the lowest range (10–20 ml/h), is a standard hypodermic cannula of 25 gauge size, 0.75 inches (19 mm) long; cannula **46***b* (20–65 ml/h), 23 gauge, 0.5 inches (13 mm) long; and cannula **46***c* (90–250 ml/h), 20 gauge, 1.25 inches (32 mm) long.

The hydrophilic and hydrophobic membranes used herein (reference numerals **66**, **78**, **80**, and **98**) should have sufficiently high break-through pressures and strengths and other satisfactory physical properties so that they can perform in the manner described above. Thus, hydrophilic membrane valve **66** should have a bubble point pressure of at least 5 psi (35 kPa). The pore size of membrane **66** may vary over a wide range, e.g., from about 0.1 to over 250 microns, smaller sizes providing the additional benefit of particulate filtering. The pore size of membrane **80** must be large enough so that the pressure drop through it is small compared to that through whichever cannula **46** is being used. Desirably membrane **66** is strong enough so that it can be compression fitted between members **158** and **160** (FIG. **10A**) to achieve the desired result without the need for any gaskets. That simplifies fabrication. Other means for retaining the membrane in place may be used, e.g., ultrasonic bonding, which is most preferred.

The device may be made of any pharmacologically acceptable material. For the rigid members (housing **110**, first chamber **28**, etc.), styrene has been found to be suitable. The tubing may be of polyvinyl chloride. Whatever the material, the tubing must be resilient enough to recover from any deformation (e.g., when tubing **86** is crimped by the tab on gear **122** during priming). Cannulae **46***a*, *b*, and *c* and dropping needles **62** and **70** may be of Inconel or type 304 stainless steel. The membranes may be of any suitable materials. Acrylic with a pluronic acid wetting agent has been found to be satisfactory for membrane **66**.

Variations and modifications will be obvious to those skilled in the art and the claims are intended to cover all modifications and variations that fall within the true spirit and scope of the invention. For example, one, two, or more than three cannulae may be used. Their sizes and the flow ranges may be changed from those described herein. Other means may be used to ensure that the primary liquid flows only through the cannula chosen. Valve **100** and header **108** may be arranged so that when secondary liquid flow commences, valve **100** halts the flow of primary liquid from header **108** to the cannula then in use. A particulate liquid outlet filter may be added to the bottom of first chamber **28**. Such a filter would need a bubble point of at least 4.5 inches (114 mm) and preferably 9–10 inches (229–254 mm) and a low pressure drop compared to that of high flow range cannula **46***c*. Any means known in the art which ensures a constant liquid head at the inlet of the cannula may be used. For example, first chamber **28** could employ an inlet float check valve to maintain the height of liquid therein within narrow limits.

I claim:

1. An apparatus for controlling the flow rate of an intravenously administered medical liquid to a patient from a supply of medical liquid, said apparatus comprising:

(a) a first chamber means for containing a portion of said liquid and a gas, having a liquid inlet, a liquid outlet, and a gas phase connection, said liquid inlet designed to receive liquid from the supply of medical fluid;

(b) a second chamber means for containing a portion of said liquid and a gas, having a liquid inlet, a liquid outlet, and a gas phase connection, said first chamber means having means for moving said first chamber means vertically with respect to the second chamber;

(c) gas phase pressure equalization means connected to the gas phase connections for equalizing the gas phase pressures in said first and second chambers;

(d) first liquid connecting means fluidly connecting the liquid outlet of the first chamber to the liquid inlet of the second chamber, said first liquid connecting means having at least one flow restrictor in the fluid flow path through which a known quantity of liquid flows when a given differential pressure exists across it;

(e) a third chamber means having a liquid outlet from which liquid passes to the patient and a liquid inlet for receiving liquid from the second chamber; and

(f) second liquid connecting means fluidly connecting the liquid outlet of the second chamber to the liquid inlet of the third chamber, said second liquid connecting means having a membrane valve in the flow path which when wet passes liquid but not gas under normal operating conditions.

2. The apparatus of claim **1** wherein a cannula is used as a flow restrictor.

3. The apparatus of claim **1** wherein the second and third chambers are in the same housing and the fluid inlet to the second chamber is fluidly connected to a dropping needle positioned above the membrane filter.

4. The apparatus of claim **1** wherein the flow restrictor provides the only significant pressure drop in the liquid flow path comprising the liquid outlet of the first chamber, the first liquid connecting means, and the liquid inlet to the second chamber.

5. The apparatus of claim **1** wherein indicia on the device for different vertical heights of the first chamber

correspond to precalibrated liquid flow rates through the flow restrictor.

6. An apparatus for controlling the flow rate of an intravenously administered medical liquid to a patient, from a supply of medical liquid, said apparatus comprising:

(a) a first chamber means for containing a portion of said liquid and a gas, having a liquid inlet, a liquid outlet, and a gas phase connection, into the gas containing part of the first chamber means said liquid inlet designed to receive liquid from the supply of medical fluid;

(b) a second chamber for containing a portion of said liquid and a gas, having a liquid inlet, a liquid outlet, and a gas phase connection, into the gas containing part of the second chamber, said first chamber means having means for moving said first chamber means vertically with respect to the second chamber;

(c) gas phase pressure equalization means for fluidly connecting the gas phase connections of the first and second chambers so as to equalize the gas phase pressures in the first and second chambers;

(d) first liquid connecting means fluidly connecting the liquid contact of the first chamber to the liquid inlet of the second chamber, said first liquid connecting means having at least one cannula in the fluid flow path through which a known quantity of liquid flows when a given differential pressure exists across it;

(e) a third chamber having a liquid outlet from which liquid passes to the patient and a liquid inlet for receiving liquid from the second chamber means; and

(f) second liquid connecting means fluidly connecting the liquid outlet of the second chamber to the liquid inlet of the third chamber, said second liquid connecting means having a membrane valve in the flow path which when wet passes liquid but not gas under normal operating conditions.

7. The apparatus of claim 6 wherein the second and third chambers are in the same housing and the fluid inlet to the second chamber is fluidly connected to a dropping needle positioned above the membrane valve.

8. The apparatus of claim 6 wherein the cannula provides the only significant pressure drop in the liquid flow path comprising the liquid outlet of the first chamber, the first liquid connecting means, and the liquid inlet to the second chamber.

9. The apparatus of claim 6 wherein indicia on the device for different vertical heights of the first chamber correspond to precalibrated liquid flow rates through the cannula.

10. An apparatus for controlling the flow rate of an intravenously administered medical liquid to a patient from a supply of medical liquid, said apparatus comprising:

(a) a first chamber means for containing a portion of said liquid and a gas, having a liquid inlet, a liquid outlet, and a gas phase connection, said liquid inlet designed to receive liquid from the supply of medical fluid;

(b) a housing having a second chamber means for containing a portion of said liquid and a gas, with a liquid inlet, a liquid outlet, and a gas phase connection, said first chamber means having means for moving said first chamber means vertically with respect to the second chamber;

(c) gas phase pressure equalization means for fluidly connecting the gas phase connections of the first and second chambers so as to equalize the gas phase pressures in those chambers;

(d) first liquid connecting means fluidly connecting the liquid outlet of the first chamber to the liquid inlet of the second chamber, said first liquid connecting means having at least one cannula in the fluid flow path through which a known quantity of fluid flows when a given differential pressure exists across it, the cannula providing the only significant pressure drop in the liquid flow path comprising the liquid outlet of the first chamber, the first liquid connecting means, and the liquid inlet to the second chamber;

(e) a third chamber means in the housing having a liquid ouetlet from which liquid passes to the patient and a liquid inlet for receiving liquid from the second chamber; and

(f) a membrane valve between the liquid outlet of the second chamber and the liquid inlet of the third chamber, the membrane valve capable of passing liquid when wet but not gas under normal operating conditions.

11. The device of claim 1 further comprising:

(a) means to connect a supply of secondary liquid to the device;

(b) means to control the flow of secondary liquid from the device to the patient;

(c) means to automatically halt the flow of primary liquid to the patient when secondary liquid flows; and

(d) means to automatically restart the flow of primary liquid to the patient after secondary liquid flow ends and at the same rate of primary flow existing prior to secondary liquid flow.

12. A method of controlling the flow of medical liquid to a patient comprising utilizing the apparatus of claim 1.

13. A method of controlling the flow of medical liquid to a patient comprising utilizing the apparatus of claim 6.

14. A method of controlling the flow of medical liquid to a patient comprising utilizing the apparatus of claim 10.

* * * * *